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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/824,782	04/15/2004	Bernardus Petrus Hubertus Peeters	2183-4646.2US	7153
24247	7590	08/10/2006	EXAMINER	
TRASK BRITT P.O. BOX 2550 SALT LAKE CITY, UT 84110			HURT, SHARON L	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 08/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/824,782	Applicant(s) PEETERS ET AL.	
	Examiner Sharon Hurt	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 6-8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 9-16 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>August 2, 2006</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-5 and 9-16, are drawn to a method for distinguishing an animal infected or vaccinated with Newcastle Disease Virus, classified in class 435, subclass 6.
- II. Claims 6-8, are drawn to a diagnostic kit for use of the method of detecting Newcastle Disease Virus, classified in class 435, subclass 7.1.

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the antigen which makes up the diagnostic kit can be used for affinity purification of antibodies.

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

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or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

During a telephone conversation with Allen Turner on Monday, July 31, 2006 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-5 and 9-16. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Affirmation of this election must be made by applicant in replying to this Office action. Claims 6-8 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claims 1-5 and 9-16 are pending and under examination.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 and 9-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Taylor et al. (Journal of Virology, Apr. 1990, Vol. 64, No. 4, p. 1441-1450) (see IDS page 4, last entry).

The claimed invention is drawn to a method for distinguishing an animal infected with wild-type Newcastle Disease Virus (NDV) or vaccinated with an unmodified mesogenic or lentogenic NDV strain of NDV or not vaccinated with NDV, from an animal, or vaccinated with a vaccine comprising an infectious copy of an avian paramyxovirus derived from NDV obtained by transfecting an avian paramyxovirus cDNA comprising an amino acid sequence corresponding to the 5'-terminal end of the genome to generate an infectious copy, wherein the copy encodes one or more viral proteins having a modification relative to wild-type, unmodified mesogenic or lentogenic NDV strain, wherein the method comprises taking at least one sample from the animal and analyzing it to determine the presence of antibodies directed against an epitope or marker expressed by a wild-type or unmodified NDV, but not by vaccine, wherein said antibodies are directed against an epitope on a hemagglutinin-neuraminidase (HN) or fusion (F) protein of NDV, wherein the modification is in a viral nucleocapsid (N), phosphoprotein (P) or large (L) protein, wherein the animal is a chicken, where said NDV is lentogenic, wherein said modification comprises a modification of a structural protein, a HN protein, or a matrix (M) protein, a modified protease cleavage site, wherein said cleavage site is a protease cleavage site of the cleavage site of the fusion protein, wherein said infectious copy of an avian paramyxovirus further comprises a nucleic acid encoding a heterologous antigen, wherein said heterologous antigen is derived from a poultry pathogen.

Taylor et al. teaches a method of detecting NDV F protein in serum samples of chickens (p. 1443). Sera samples were collected from vaccinated and non-vaccinated

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chickens and tested for the presence of anti-FPV (fowlpox virus used as a vector) antibodies by using ELISA (p. 1443). Taylor teaches that the cleavage of the F protein is important in determining the pathogenicity of a NDV strain and the amino acid sequence at the cleavage site is therefore critical in determining viral virulence (p. 1444). A comparison of the sequence differences can differentiate the avirulent strains from the virulent strains therefore distinguishing the vaccinated from unvaccinated chickens and wild-type NDV from unmodified or lentogenic strain of NDV (p. 1448-1449).

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Stauber et al (Vaccine, 1995, Vol. 13, No. 4, p. 360-364) (see IDS page 6). Stauber et al. teaches a method for detecting NDV in poultry vaccines using RT-PCR and direct nucleotide sequencing of amplified DNA (Abstract).

Nagy et al. (Canadian Journal of Veterinary Research, 1993, Vol. 57, p. 306-308). Nagy et al. teaches about the vaccination of chickens with a recombinant fowlpox virus (FPV) containing the HN gene of NDV and detection of the antibody by ELISA comparing the response of the chickens vaccinated with FPV and the recombinant virus (p. 307).

Conclusion

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon Hurt whose telephone number is 571-272-3334. The examiner can normally be reached on M-F 8:00 - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sharon Hurt

7 August 2006


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